

REVISED 4/24/02

DEPARTMENT OF HEALTH AND HUMAN SERVICES
MEETING OF THE
NATIONAL HUMAN RESEARCH PROTECTIONS ADVISORY COMMITTEE (NHRPAC)

MONDAY, APRIL 29 & TUESDAY, APRIL 30, 2002
HILTON WASHINGTON EMBASSY ROW
AMBASSADOR ROOM
2015 MASSACHUSETTS AVENUE, NW
WASHINGTON, DC 20036
202/265-1600

AGENDA

Monday, April 29, 2002

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| 8:30am – 8:35am | WELCOME: OVERVIEW OF MEETING Mary Faith Marshall, Ph.D. Chairperson, NHRPAC |
| 8:35am – 9:00am | OPENING REMARKS Edward D. Miller, M.D. Dean, Medical Faculty and Chief Executive Officer Johns Hopkins Medicine |
| 9:00am – 11:00am | CHILDREN'S WORK GROUP: MINIMAL RISK, MINOR INCREMENT OVER MINIMAL RISK, & DISORDER/CONDITION Alan Fleischman, M.D. Chair, Children's Workgroup Senior Vice President The New York Academy of Medicine |
| [10:15am – 10:30am] | BREAK |
| 11:00am – 11:15am | CLASSIFIED RESEARCH – UPDATE Greg Koski, M.D., Ph.D. Director, Office for Human Research Protections |

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| 11:15am – 12:00am | <p>HIPAA: NHRPAC RESPONSE TO HHS NPRM AMENDING THE FINAL HIPAA REGULATION</p> <p>Mark Barnes, J.D., LL.M. Partner Ropes & Gray</p> |
| 12:00pm – 1:00pm | LUNCH |
| 1:00pm – 1:30pm | <p>PESTICIDE TESTING IN HUMANS – UPDATE ON HUMAN STUDIES ISSUES AT EPA</p> <p>William Jordan, J.D. Senior Policy Advisor Office of Pesticide Programs Environmental Protection Agency</p> |
| 1:30pm – 3:00pm | <p>PESTICIDE TESTING IN HUMANS – OTHER PERSPECTIVES</p> <p>Moderator: Mary Faith Marshall Richard Wiles Senior Vice President Environmental Working Group Douglas Nelson, Ph.D., J.D. Senior Vice President and General Counsel Crop Life America Russell Katz, M.D. Director of Neuropharmacologic Drug Products Center for Drug Evaluation & Research Food & Drug Administration</p> |
| 3:00pm – 3:30pm | TBD |
| 3:30pm – 3:45pm | BREAK |
| 3:45pm – 5:30pm | <p>UPDATE: INFORMED CONSENT–DISCUSSION OF THREE ISSUES:</p> <p>Tom Beauchamp, Ph.D. Professor of Philosophy, Georgetown University Senior Research Scholar, Kennedy Institute of Ethics Elliot Dorff, Ph.D. Co-chair workgroup</p> |
| 5:30pm | ADJOURN |

Tuesday, April 30, 2002

8:30am - 8:45am

RECAP

Mary Faith Marshall

8:45am – 10:15am

UPDATE AND DISCUSSION: GENETICS WORKGROUP

Mary Kay Pelias, J.D., Ph.D.

Chair, Working Group
Professor of Genetics,
Louisiana State University, HSC

[10:15am – 10:30am]

BREAK

10:30am – 12:30pm

PRAXIS AND ACTION: CONDUCT OF RESEARCH IN THE AFTERMATH OF
BIOTERRORISM

Moderator:

Jonathan Moreno, Ph.D.

Monica Schoch-Spana, Ph.D.

Senior Fellow

Center for Civilian Biodefense Strategies
Johns Hopkins University

John Livengood, M.D.

Deputy Associate Director for Science
Centers for Disease Control and Prevention

12:30pm – 1:30pm

LUNCH

1:30pm – 2:30pm

WORKGROUP ON DECISIONAL CAPACITY

Jonathan Moreno, Ph.D.

Director, Center for Biomedical Ethics
University of Virginia Health System

2:30pm – 4:15pm

UPDATE AND DISCUSSION: SOCIAL & BEHAVIORAL SCIENCE WORK
GROUP

Felice Levine, Ph.D.

Co-chair Working Group
Executive Officer
American Sociological Association

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| | Jeffrey Cohen, Ph.D. Co-chair, Working Group Director, Education, OHRP/HHS |
| [3:00pm - 3:15pm] | BREAK |
| 4:15pm – 4:30pm | WRAP-UP Mary Faith Marshall |
| 4:30pm | ADJOURN |